

# The Impact of Web Based Education on Attitudes and Outcomes in Patients Taking Warfarin

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## Abstract

**Background:** Patients taking warfarin are at risk for thromboembolic events when not in a therapeutic international normalized ratio (INR) range. Patient's lack of understanding regarding their medication and illness often leads to non-adherence to medication, which can lead to adverse events. In a retrospective cohort study, the Lehigh Valley Physicians Group (LVPG) Anticoagulation Clinic will be able to analyze the impact of implementing a web-based educational application that can be accessed from the patient's home. The objective is to educate warfarin-naïve patients on their treatment in order to keep patients in a therapeutic INR range and reduce the risk of adverse events.

**Methods:** In a retrospective cohort study, Lehigh Valley Physicians Group (LVPG) Anticoagulation Clinic will provide access to web-based education to patients requiring first time treatment with the oral anticoagulant, warfarin. These patients will be followed for one year to capture % time in therapeutic range and the frequency of adverse events such as stroke, gastrointestinal bleed, deep vein thrombosis (DVT), pulmonary embolus (PE), myocardial infarction (MI), hospital re-admissions, and hospitalizations. Patient outcomes in the study group will be compared to outcomes in warfarin naïve patients that do not take part in the web-based education. Secondary outcomes will include patients' perception on their quality of life, severity of anxiety and depression, their knowledge regarding understanding of their illness and medication prior to and after education. Surveys will be captured at baseline and six months. Surveys include the Palliative Outcome Scale (POS), to measure quality of life, Patient Health Questionnaire (PHQ-9) to assess their depression score, Generalized Anxiety Disorder 7 Item Scale (GAD-7) to assess their anxiety score, and Patient Activation Measure® (PAM®) which will measure the patient's knowledge and perception of both their medication and illness. A community care team (CCT) will be joining LVPG Cardiology to assist with the management of patients with Congestive Heart Failure (CHF). Team members will be consulted when patients are identified in the study as having anxiety, depression, poor coping skills, a poor understanding of their warfarin medication, financial issues, or lack of social support at home. These patient outcomes will be analyzed separately to determine effectiveness of the CCT on this patient population.

**Conclusions:** Both the web-based education and the CCT installment in the LVPG Anticoagulation Clinic aim to decrease overall hospital admissions and readmissions thereby cutting costs and satisfying the requirements for the Hospital Readmission Reduction Program under the Affordable Care Act. With the objective of decreasing adverse events, keeping patients in a therapeutic INR range, and encouraging patients to be proactive and knowledgeable in regards to their treatment, both the web-based education and CCT have the intention of achieving the three goals specified by the Triple Aim; better cost, better health, and better care.

## Introduction

Patients with diagnoses such as atrial fibrillation, deep vein thrombosis (DVT), mechanical valve replacements, pulmonary embolus (PE), venous thromboembolism (VTE), myocardial infarction (MI), peripheral arterial occlusion, and stroke may require the use of anticoagulants to prevent the occurrence or reoccurrence of a thrombotic events (Johnson; "Point-of-Care International

Normalized Ratio (INR) Monitoring Devices for Patients on Long-term Oral Anticoagulation Therapy: An Evidence-Based Analysis," 2009). Anticoagulants prevent the coagulation or clotting of blood. In the United States, an estimated 2.6 million people have atrial fibrillation and 900,000 VTE events occur annually (Mahan et al., 2012). Today there are numerous oral anticoagulants on the market, but the vitamin K antagonists (VKA) remain the

most popular with over 60 years of use in treating thromboembolic events (Yates & Sarode, 2015). Vitamin K antagonists act by reducing the action of vitamin K. Vitamin K antagonists need to be closely monitored due to their narrow therapeutic index and various food and drug interactions (DynaMed, 2015). If not closely managed, patients can fall outside of the set goal. If the INR is too high, this increases the patients risk of hemorrhage and if the INR is too low, the patient is at risk for a thromboembolic event (Johnson). When oral anticoagulants are poorly controlled, there is a significant increase for the risk of death, ischemic stroke and thromboembolic events. Approximately 90% of warfarin-related deaths are caused by intracranial hemorrhage due to complications of VKA oral anticoagulants (Yates & Sarode, 2015). For patients on warfarin, the frequency of bleeding events is approximately between 15 and 20% annually (Zareh, Davis, & Henderson, 2011). However, when properly managed, oral anticoagulants can significantly decrease the frequency of stroke by more than two thirds (Pokorney et al., 2015).

In North America, warfarin is the most commonly prescribed oral anticoagulant and is also frequently prescribed worldwide (Shuaib, Iftikhar, Alweis, & Shahid, 2014). Annually, there are 30 million prescriptions for warfarin with total direct expenditures estimated to be 158 million dollars per quarter (Kirley, Qato, Kornfield, Stafford, & Alexander, 2012; Wysowski, Nourjah, & Swartz, 2007). Warfarin decreases the risk of ischemic stroke by 67% and death by 25% (Gladstone et al., 2009). In order to promote the safety and effectiveness of warfarin, patients need to stay in therapeutic range (TTR) with an international normalized ratio (INR) of 2.0-3.0 (Pokorney et al., 2015) or 2.5-3.5 for mechanical mitral valves (Kardon, n.d.). Previous research has shown that the minimum time spent in therapeutic INR range

needs to be >58% in order for warfarin to be effective (Smith, Xuereb, Pattison, Lip, & Lane, 2010). Data has shown that when patients' INRs are in therapeutic range for 70% of the time, their risk of stroke reduces by 79%, compared to those who spent less than 30% of their time within range (Gallagher, Setakis, Plumb, Clemens, & van Staa, 2011). When properly managed, warfarin is highly effective. However, patient adherence and knowledge of their drug treatment often serves as a barrier to its effectiveness.

It was found that during the first three months of treatment for warfarin-naïve patients, that half of thrombotic events occurred during this time frame (Palareti et al., 1997). These events can be attributed to numerous factors, those of which include patient knowledge and perception of their condition and treatment, non-adherence to medication, lifestyle habits such as diet and alcohol consumption, and compliance (Baker, Pierce, & Ryals, 2011). For example, a study conducted by Shuaib et al. on patients' knowledge of their drug regimen found that 56% of patients were unaware of any warfarin drug interactions, 70% were not acquainted with the term INR, and 58% were not aware of adverse effects (Shuaib et al., 2014). Studies have also shown that there is a direct correlation between patient knowledge and their time spent in therapeutic INR range (Tang et al., 2003). Previous research exhibits that patients managed in an anticoagulation clinic versus those who were not, spent significantly more time in therapeutic range (van Walraven, Jennings, Oake, Fergusson, & Forster, 2006). In order to increase adherence and decrease thromboembolic events, warfarin-naïve patients should be formally educated and closely monitored by an anticoagulation clinic.

Under the Affordable Care Act, Medicare is authorized to decrease payments to hospitals that have a high percentage of hospital readmissions.

The program pays specific attention to high-risk and high cost patients, such as those with pneumonia, heart attack, heart failure, chronic obstructive pulmonary disease (COPD), and hip/knee replacement (Center for Medicare and Medicaid Services, 2015). Readmissions are calculated using a ratio of hospital predicted 30-day readmissions by the expected readmissions based on similar hospital averages. Medicare states that a high volume of readmissions can be attributed to inadequate care coordination and follow up care in the community (Center for Medicare and Medicaid Services, 2015). At Lehigh Valley Health Network, the department of Population Health consists of community care teams (CCT) who are placed in primary care practices that are transitioning into patient-centered medical homes (PCMH). Community Care Teams consist of social workers, pharmacists, nurse care managers, and behavioral health specialists (Foltz et al., 2014). Community Care Teams directly manage high-risk patients in order to increase practice effectiveness and efficiency as well as improve patient outcomes. These outcomes include decreased hospitalizations, patient satisfaction and decreased medical costs. In a study conducted by Foltz et al., they found that practices containing CCT's reduced the probability of admission and readmission compared to those without CCT's (Foltz et al., 2014). By improving the quality of care, CCT's help to coordinate care and reduce both admissions and readmissions, thus assisting in meeting the criteria for the Hospital Readmission Reduction Program under the Affordable Care Act (Figure 1). In the upcoming months, a CCT will be implemented in the LVPG Cardiology and to include patients seen in the anticoagulation clinic to manage high-risk congestive heart failure (CHF) patients, for now. If shown effective, this may expand to other patients with high-risk disease.

In a study conducted by Liles et al., they found that at baseline, two of the most common causes for readmission were medication non-adherence and lack of patient understanding (Allen Liles, Moore, & Stein, 2015). Through the web-based education system, patients new to warfarin will be encouraged to stick to their medication regimen and be made aware of the thromboembolic events, which may occur as result of medication non-compliance. Patients will also be thoroughly educated on their condition and treatment in order to increase understanding in hopes of decreasing readmissions and adverse events. Through both the web-based education system and the CCT, the LVPG anticoagulation clinic aims to improve patient outcomes and decreases readmissions in order to ensure the highest quality of care encouraged under the Affordable Care Act.

In a retrospective cohort study, the Lehigh Valley Physicians Group (LVPG) Anticoagulation Clinic will analyze the impact of implementing a web-based educational application system that can be accessed from the patient's home and when its most convenient for the patient. The objective is to educate warfarin-naïve patients on their concepts related to "taking warfarin" in order to reduce the risk of adverse events and more time spent in therapeutic INR range. This study will also look at secondary outcomes, including health-related quality of life, anxiety and depression scores, hospitalizations and readmissions, and patient knowledge and perception of medication and illness prior to and after education.

## **Methods**

### **Study Design**

This will be a retrospective, cohort study of patients who are managed at the LVPG Anticoagulation Clinic and who are diagnosed

with a condition requiring first-time treatment with the oral anticoagulant warfarin. Study participants must be at least 18 years of age, have no cognitive deficiencies, be willing to participate and attend follow-up visits in the clinic for one year, and have no life-threatening illnesses with life expectancy <1 year. In order to complete the web-based education, patients must have at-home access to technology. This includes computers, cell phones or a tablet. Those without access or those who do not complete the education will be used as a control group for comparison. Patients new to warfarin will be sent an e-mail containing an access code to the web-based educational system where they will receive in-depth education regarding their treatment. If the patients do not use email, a letter will be generated that includes the web site to access the information along with an access code. The education consists of five (5), brief modules that very simply review important concepts on taking warfarin safely and effectively. The patient will have the ability to access and view the web-based education at home, at a time that is best suited for them and allows more time to concentrate and understand the concepts. Time spent in therapeutic INR range and the frequency of adverse events such as hemorrhagic or embolic stroke, gastrointestinal bleed, DVT, PE, MI or re-hospitalization, of warfarin-naïve patients will be captured and compared between groups; those who receive educational intervention using the web-based technology compared to warfarin-naïve patients who are not educated using the technology. Secondary outcomes will include patients' perception on their quality of life, severity of anxiety and depression, their knowledge regarding understanding of their illness and medication prior to and after education. Surveys will be captured at baseline and six months. Surveys include the Palliative Outcome Scale (POS), to measure quality of life, Patient Health Questionnaire (PHQ-9) to assess

their depression score, Generalized Anxiety Disorder 7 Item Scale (GAD-7) to assess their anxiety score, and Patient Activation Measure® (PAM®) which will measure the patient's knowledge and perception of both their medication and illness.

As part of the Patient Centered Medical Home, a community care team (CCT) will be joining LVPG Cardiology to assist with the management of patients with Congestive Heart Failure. (CHF) This team will include a social worker, pharmacist, nurse care manager, and a behavioral health specialist. The team members will assist in managing these high-risk patients in order to improve patient outcomes. Community Care Teams members will be consulted to assist with those patients identified in the study as having anxiety, depression, poor coping skills, a poor understanding of their warfarin medication, financial issues, or lack of social support at home. These patient's outcomes will be analyzed separately to determine effectiveness of the CCT on this patient population.

### **Materials and Procedures**

At the patient's first visit to the LVPG Anticoagulation Clinic they will be provided the education website and a patient specific access code. If the patient does not have access to email, they will be given a letter that provides the web address as well as the access code. The web-based education system will consist of five modules that will be available in both English and Spanish and takes approximately twenty minutes to complete. The focus of the modules is to educate patients on how to safely and effectively take warfarin. These modules include videos that cover the basics of taking warfarin, managing your medications, monitoring warfarin, what can affect warfarin, and how to stay safe while taking warfarin. Patients will have the ability to watch the modules at home at

their leisure at a time most suitable for learning. If the patient has any difficulties operating technology or the web-based education, family members are encouraged to join in and assist with the learning process.

During the first visit and at six (6) months, patients will be given the following questionnaires. The Palliative Outcome Scale (POS) questionnaire to assess their quality of life (QoL) The questionnaire is available in eleven languages and asks the patient ten questions regarding their disease state and how it affects them physically, psychologically, emotionally and spiritually. The scores from each question are totaled and the overall score represents the necessity for clinical attention. The questionnaire is most beneficial when given periodically over time in order to recognize any changes in the patients QoL that require clinical attention (Cicely Saunders Institute, 2012). The Patient Health Questionnaire (PHQ-9) to assess their depression score. The questionnaire consists of nine questions with answers ranging on a scale from 0-3. All checked boxes are added to establish the patients total score which is then used to determine depression severity (Kroenke, Spitzer, & Williams, 2001). The Generalized Anxiety Disorder 7 Item Scale (GAD-7) to assess their anxiety score. The questionnaire consists of seven questions that screen for panic disorder, social anxiety disorder and post-traumatic stress disorder (PTSD). Patients rate on a scale from 0-3 how difficult their daily tasks are such as work, communicating with others and accomplishing things at home. Their total score is then used to interpret the severity of their anxiety (Spitzer, Kroenke, Williams, & Löwe, 2006).

Patient's knowledge and perception of both their medication and illness will be evaluated using the Patient Activation Measure® (PAM®) score, which is available in twenty-two languages. Patients are scored between 0-100

and fall into one of four levels that represent their activation. Level 1 patients are considered disengaged and overwhelmed, level 2 are becoming aware but still struggling, level 3 are taking action, and level 4 are maintaining behaviors and pushing further (Insignia Health, 2015). The PAM® score helps to predict health behaviors and outcomes and is an indicator at how well patients are able to manage their treatment. The PAM® score will be given pre and post education. Those patients who do not complete the education will complete the Patient Activation Measure® pre and post first visit to the LVPG Anticoagulation Clinic.

### Endpoints

International normalized ratios will be monitored during the patients visit to the LVPG Anticoagulation Clinic or as recommended by their practitioner. These INR's can be obtained either at a local lab, from a home based monitoring device, or at the LVPG Anticoagulation Clinic. These INR results will be logged into the patient's electronic medical record. As part of our analysis, all INR's for one year will be captured. The goal is to keep patients in a therapeutic INR range of 2.0-3.0 and 2.5-3.5 for patients with mechanical heart valves, or as directed by the ordering physician. Time spent in therapeutic INR will be calculated using the percent of visits in range. This is calculated by taking the number of visits the patient had INR results in range, divided by the total number of visits. Adverse events such as hemorrhagic or embolic stroke, gastrointestinal bleed, DVT, PE, MI or re-hospitalization will be measured using patients' records through EPIC electronic health record software or patient reported information. Patients who complete the web-based education will be tracked through EPIC and logged under "other-orders." A monthly report is also sent out to the director of

Population Health, the Advanced Practice Nurses in the LVPG Coumadin Clinic, and Lehigh Valley Health Network (LVHN) steering committee stating the percentage of patients who completed the web-based education. Results from the QoL, GAD-7, PHQ-9, and PAM® surveys will be captured and analyzed and reported out in percentages.

## Results

Research shows that patients need to be in a therapeutic INR range for more than 58% of the time in order for their warfarin treatment to be effective (Smith et al., 2010) and data has shown that when patients' INRs are in therapeutic range for 70% of the time, their risk of stroke reduces by 79%, compared to those who spent less than 30% of their time within range. The LVPG Anticoagulation Clinic will measure a patient's time spent in therapeutic INR range by taking the number of visits that the patient had INR results in range and dividing it by the total number of visits. This will allow the clinic to analyze the impact of the web-based education on patients INR's and compare them to patients who did not receive the education.

Patients can be identified as having completed or did not complete the web-based education via the EPIC electronic medical record. This will assist in differentiating groups.

Adverse events will be abstracted from the EPIC electronic medical record. Number of occurrences for each adverse event will be compared amongst groups including the group who receives the education, the group with no education and the CHF group.

The POS questionnaire, the PHQ-9, and the GAD-7 will each be analyzed based on their scoring criteria and results will be captured and compared amongst groups. The PAM® score will be utilized to test patients' knowledge and

understanding of their medication and illness and results compared amongst groups.

The web-based education also seeks to improve patient knowledge and perception of their medication and illness thereby increasing their quality of life, decreasing their anxiety and depression, and ensuring their safety. With the implementation of a CCT within the LVPG Anticoagulation Clinic, outcomes are expected to improve among the high-risk CHF patients whose care will be closely managed by members of the CCT. After the INR's from baseline to one year are analyzed, the clinic will have a better understanding of the effectiveness of web-based education on patients new to warfarin.

## Conclusion

Atrial fibrillation and thromboembolic events are a common occurrence and affect many people in the United States. Despite the new oral anticoagulants on the market today, warfarin remains the most commonly prescribed oral anticoagulant. Given the narrow therapeutic range of warfarin, it is imperative that patients adhere to their medication regimen and stay within their therapeutic range. Patients who fall outside of this range are at risk for adverse events. Knowledge and understanding of warfarin and its effects can be a barrier to the patient's success while taking warfarin. Research has shown that there is a direct correlation between patient knowledge and time spent in therapeutic range, therefore, the more time spent in therapeutic range, the less adverse outcomes. Our study sets out to determine if a web-based educational application that teaches patients new to warfarin about their illness and the importance of medication adherence will result in less adverse events. Both the web-based education and the CCT installment in the LVPG Anticoagulation Clinic aim to decrease overall hospital admissions and readmissions thereby cutting costs and satisfying the

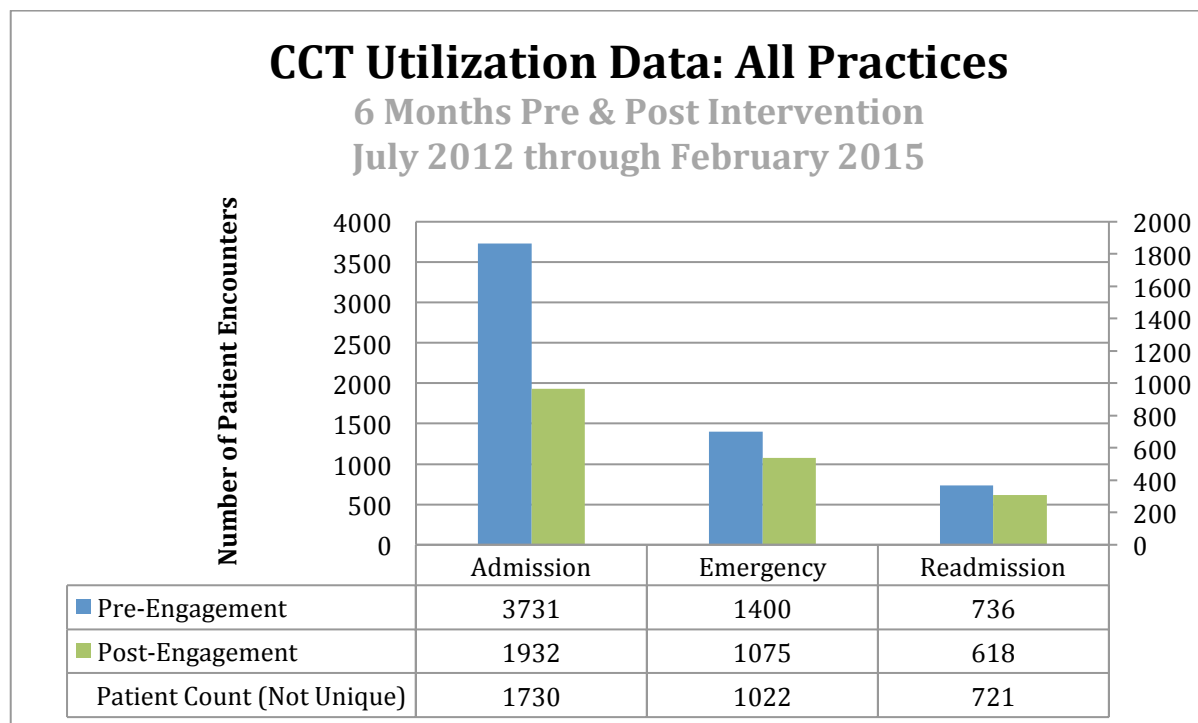
requirements for the Hospital Readmission Reduction Program under the Affordable Care Act. With the objective of decreasing adverse events, keeping patients in a therapeutic INR range, and encouraging patients to be proactive and knowledgeable in regards to their treatment, both the web-based education and CCT have the intention of achieving the three goals specified by the Triple Aim; better cost, better health, and better care.

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**Figure 1. The number of admissions, emergencies, and readmissions, pre and post intervention by the Lehigh Valley Health Network Community Care Team (Shull, 2015).** The graph depicts outcomes including hospital admissions, hospital readmissions and Emergency Department visits before and after management by the Community Care Team.